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H/A

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/512,926 02/25/00 LAMB

F P-1057

HM12/1010  
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EXAMINER

KIM, T	ART UNIT	PAPER NUMBER
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1617

DATE MAILED:

10/10/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/512,926	LAMB, FRED S.
	Examiner	Art Unit
	Jennifer M Kim	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 July 2001.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 14-21 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-13 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a)  The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
- 4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_ .
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other:

## DETAILED ACTION

Applicant's election without traverse of claims 4-11 drawn to a method of ameliorate the negative effects associated with vascular smooth muscle endothelium damage comprising administering a CLC3 blocker in Paper No.3 is acknowledged. Accordingly, the elected claims (4-11) have been examined among with generic claims 1-3, 12 and 13, and the generic claims have been examined only to the extent of the elected separate and distinct invention. Remaining claims 14-21 are withdrawn from consideration as being non-elected claims.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific CLC3 blocker disclosed, does not reasonably provide enablement for the term "a CLC3 blocker". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The

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term "a CLC3 blocker" in claims 1 and 4 lacks clear exemplary support in the specification as filed.

The remaining claims are rejected to the extent that they depend on claims 1 and 4.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 3, 4, and 6-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "the negative effects" renders claim 4 indefinite because it is unclear what are "the negative effects" the Applicant is referring to since the phrase is not described in the specification.

5. The parenthetical terms in claims 3,6 and 13 are redundant.

The remaining claims are indefinite to the extent that they depend on claim 4.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lamb (May 1995) of record.

Lamb on page 1, third paragraph, teaches tamoxifen normalized the sensitivity of the contractile of intact endothelium and rubbed vessels in response to NE and KCL.

Lamb on page 2, first paragraph, teaches tamoxifen reverses a process which is induced by damaged to the endothelium causing increase in vascular smooth muscle (VMS) contractility.

Lamb on page 2, first paragraph, teaches tamoxifen normalizes vascular reactivity by shut down CLC-3 channels and return the vascular smooth muscle to its "normal" state.

Lamb on page 2, third paragraph teaches pathological activation of CLC3 may be relevant to multiple clinical disease states which are associated with endothelial dysfunction including coronary artery disease, diabetes and hypertension.

The reference differ from Applicant's claiming invention in that employing tamoxifen to an endothelialy-compromised VSM patient in need of reduction in sensitivity of endothelium of VSM and to a patient with vascular smooth muscle endothelium damage and further administering other agents known to treat the diseases cause endothelium damage set forth in claims 7-11.

However, that applicant may have determined a mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated and the effect are

the same. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims.

To combine pharmaceutically active agents that are known to treat the diseases set forth in claims 7-11 are all within the knowledge of the skilled artisan in order to achieve at least additive effect.

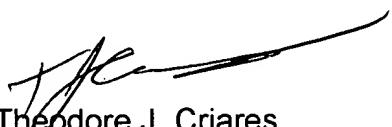
For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is (703) 308-2232. The examiner can normally be reached on Monday through Friday from 9 AM. to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Theodore J. Criares  
Primary Examiner  
Art Unit 1617

jmk  
October 3, 2001